The Technical Advisory Group's Evaluation of Pertussis, Diphtheria, and Tetanus against the Nine Criteria

The Technical Advisory Group (TAG) met on May 17, 2006 to evaluate pertussis, diphtheria, and tetanus (Tdap) against nine evaluation criteria. Below are brief summaries of deliberations and ratings of these three antigens against the nine criteria. The TAG paid special attention to Tdap during its deliberations because replacing the *2005 Recommended Childhood and Adolescent Immunization Schedule* with the 2006 schedule in WAC 246-100-166, would have the effect of requiring an adolescent Tdap vaccine instead of the currently required tetanus booster.

The Technical Advisory Group recommends that pertussis, diphtheria, and tetanus be retained in WAC 246-100-166 and that the rule be updated to incorporate the 2006 Recommended Childhood and Adolescent Immunization Schedule.

Pertussis and diphtheria met all nine of the criteria. Tetanus met eight out of nine of the criteria, and was still recommended by the Technical Advisory Group for retention in WAC 246-100-166.

Evaluation of Pertussis against the Nine Criteria

Criteria	Criteria Met?	Comment
A vaccine containing this antigen is recommended by the ACIP and included on its Recommended Childhood & Adolescent Immunization Schedule.	Yes	A vaccine containing this antigen is listed in the 2006 Recommended Childhood and Adolescent Immunization Schedule.
The antigen is effective (in terms of immunogenicity and population-based prevention).	Yes	The immunogenicity data support effectiveness. There is scientific evidence which indicates that acellular pertussis vaccines are effective for the pre-school populations. European countries that use whole-cell pertussis vaccines have administered them to older children. Studies have shown that they have been effective in reducing the incidence of pertussis among older children. Canada's experience also suggests that it is effective in this age group. Based on this evidence, the TAG considers that Tdap is probably effective at preventing pertussis in older children.
The vaccine containing this antigen is cost effective (from a societal perspective) as compared to other vaccines associated with diseases included in WAC 246-100-166.	Yes	The data indicate that the cost effectiveness is comparable to other vaccines for other diseases listed in WAC 246-100-166.
Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of side effects.	Yes	Pre-licensure study findings demonstrated safety and efficacy against tetanus, diphtheria, and pertussis when Tdap was administered as a single-dose booster to adolescents. Findings from pre-licensure studies were comparable to Td. Analysis of post-marketing VAERS reports suggest comparable safety to Td, including no occurrences of serious complications.

The vaccine containing this antigen prevents diseases with significant morbidity and/or mortality implications (in some sub-set of the population).	Yes	Pertussis remains a major problem in Washington, and we consistently have a rate of disease that is higher than the national average. In 2004, our rate of pertussis was 13.7 cases per 100,000, more than twice the US rate of 6.5. From 1995 through 2004, the mean age jumped to 10.5 -- meaning that the average person with pertussis in Washington is getting older, and the same thing is being seen nationally.
Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.	Yes	By preventing the cough associated with pertussis, the spread of the illness is likely reduced.
The vaccine is acceptable to the medical community and the public.	Yes	Physician acceptance has been excellent - many have seen a patient with pertussis and wish to prevent the disease. Administering Tdap provides an opportunity to conduct a well child visit which has health returns for the child (and is well reimbursed for the care provider). The public has expressed little vocal resistance and no unusual concern.
The administrative burdens of delivery and tracking of vaccine containing this (these) antigen(s) are reasonable.	Yes	DOH has not expressed undue concerns about administrative burdens. Many schools are already overwhelmed by managing immunization compliance. Introduction of this vaccine will necessitate changes and so create a front loaded burden for schools. However, despite a heavy workload many school nurses still see the health benefits of providing protection against these diseases.
The burden of compliance for the vaccine containing this antigen is reasonable for the parent/caregiver.	Yes	It is easier to vaccinate a patient than to care for one. Tdap is not an additional vaccine, it simply replaces Td. Since administering Tdap can be combined with a well child visit, it is not an additional burden. The burdens of compliance are offset by the benefits. However, the TAG recognized that this (as is true for any vaccine compliance) may pose the greatest burden for the working poor.

Evaluation of Diphtheria and Tetanus against the Nine Criteria

Criteria	**Criteria Met?**	**Comment**
A vaccine containing this antigen is recommended by the Advisory Committee on Immunization Practices and included on its Recommended Childhood & Adolescent Immunization Schedule.	Yes	A vaccine containing these antigens is listed in the 2006 Recommended Childhood and Adolescent Immunization Schedule.

The antigen is effective (in terms of immunogencity and population-based prevention).	Yes	Essentially we no longer see cases of diphtheria or tetanus in the USA. However, these diseases still exist in countries with weak vaccination programs.
The vaccine containing this antigen is cost effective (from a societal perspective) as compared to other vaccines associated with diseases included in WAC 246-100-166.	Yes	The data indicate that the cost effectiveness is comparable to other vaccines for other diseases listed in WAC 246-100-166.
Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of side effects.	Yes	We have lots of experience with vaccines containing these antigens and consistently find them to be very safe.
The vaccine containing this antigen prevents diseases with significant morbidity and/or mortality implications (in some sub-set of the population).	Yes	Diphtheria and tetanus are both diseases with significant morbidity and/or mortality implications.
Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.	Yes for diphtheria No for tetanus	Exposure to diphtheria remains possible during travel to countries where diphtheria is endemic or from imported cases. Vaccinating reduces the risk of person-to-person transmission. Diphtheria is an acute bacterial disease that is highly communicable. Tetanus is the only vaccine-preventable disease that is not communicable but acquired through environmental exposure to the spores of Clostridium tetani. If a pregnant mother is vaccinated, her antibodies protect the infant from neonatal tetanus, even if there's an environmental exposure when the umbilical cord is cut.
The vaccine is acceptable to the medical community and the public.	Yes	There is a high degree of acceptance of these 2 antigens by both the medical community and the public.
The administrative burdens of delivery and tracking of vaccine containing this (these) antigen(s) are reasonable.	Yes	Td is already recommended, so there are no major changes in administrative burdens.
The burden of compliance for the vaccine containing this antigen is reasonable for the parent/caregiver.	Yes	It is easier to vaccinate a patient than to care for one. Tdap is not an additional vaccine, it simply replaces Td. Since administering Tdap can be combined with a well child visit, it is not an additional burden. The burdens of compliance are offset by the benefits. However, the TAG recognized that this (as is true with any vaccine compliance) may pose the greatest burden for the working poor.